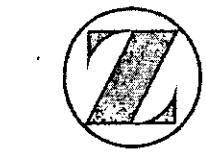
K122529 (1/3)



NOV 16 2012

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Mark D. Warner Senior Specialist, Regulatory Affairs Telephone: (574)-372-4150 Fax: (574) 372-4605
Date:	August 17, 2012
Trade Name:	*Zimmer*® Unicompartmental Knee System *Vivacit-E*® Articular Surface
Product Code / Device:	HSX – Prosthesis, knee, femorotibial, non-constrained, cemented, metal/polymer OIY – Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive / metal / polymer + additive
Regulation Number / Description:	21 CFR § 888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis 21 CFR § 888.3560 – Knee joint, patellofemorotibial, polymer / metal / polymer, semi-constrained, cemented prosthesis
Predicate Device:	*Zimmer* Unicompartmental Knee System, manufactured by Zimmer, Inc. (K033363, cleared January 6, 2003) *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners, manufactured by Zimmer, Inc. (K120370, cleared June 4, 2012)

	E1™ Antioxidant Infused Technology, Manufactured by Biomet Manufacturing Corp. (K100048, cleared March 9, 2010)
Device Description:	The *Zimmer* Unicompartmental Knee System (ZUK) is a prosthesis that replaces only one compartment of the knee condyles. It is unconstrained in the anteroposterior and mediolateral directions and also allows unconstrained internal/external rotation between the femoral and tibial components. This movement is limited only by the ligaments and other soft tissues surrounding the device.
Intended Use:	The *Zimmer* Unicompartmental Knee System is indicated for patients with: - Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis. - Previous tibial condyle or plateau fractures with loss of anatomy or function. - Varus or valgus deformities. - Revision of previous arthroplasty procedures. These devices are indicated for cemented use only. The *Zimmer* Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.
Comparison to Predicate Device:	The proposed *Zimmer* Unicompartmental Knee System components are similar or identical in intended use, materials, sterility, and performance characteristics to the predicate devices.
Performance Data (Nonclinical and/or Clinical):	Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device. Non-Clinical Performance and Conclusions: *Vivacit-E* material characteristics for the *Zimmer* Unicompartmental Knee System (ZUK) are identical to the predicate Zimmer *Vivacit-E* Acetabular Polyethylene Liners (K120370). In contrast to conventional polyethylene, the *Vivacit-E* material is delamination resistant and exhibits a

reduction in wear according to knee simulator bench testing.

Bench testing outlined in table 1, below, was conducted according to FDA guidance documents:

Table 1: Bench Performance Testing Overview

Property or Characteristic	Test Results
Effect of prolonged aging on the wear performance of vitamin-E IT Liner	Demonstrated that prolonged accelerated aging does not significantly affect wear performance of Vivacit E material.
Evaluation of the Delamination Resistance of *Vivacit-E* Ultra High Molecular Weight Polyethylene	Demonstrated that Vivacit E material is delamination resistant.
Wear Testing of Zimmer Unicompartmental Knee (ZUK) *Vivacit-E* UHMWPE Articular Surfaces under Load and Motion Curves from the ISO-14243 Standard, Report	Demonstrated that the wear characteristics of the *Zimmer* Unicompartmental Knee *Vivacit-E* articular surfaces are sufficient to survive expected *in vivo* loading conditions.
Fatigue Evaluation of the Zimmer Unicompartmental Knee (ZUK) *Vivacit-E* UHMWPE Articular Surface Locking Mechanism	Demonstrated adequate resistance of the modular articular surfaces to disassembly.
ZUK VE Posterior Edge Crush Fatigue Strength Evaluation	Demonstrated posterior edge crush fatigue strength is sufficient to survive expected *in vivo* loading conditions.
Human Factors Comparison of Manual Assembly of the Zimmer Unicompartmental Knee (ZUK) *Vivacit-E* UHMWPE Articular Surfaces	Demonstrated that assembly force required to insert the *Zimmer* Unicompartmental Knee *Vivacit-E* articular surfaces is appropriate for users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Zimmer, Incorporated
% Mr. Mark D. Warner
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Letter Dated: November 16, 2012

Re: K122529
Trade/Device Name: Zimmer® Unicompartmental Knee System Vivacit-E® Articular Surface
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX, OIY
Dated: August 17, 2012
Received: August 20, 2012

Dear Mr. Warner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122529

Device Name: Zimmer Unicompartmental Knee System

Indications for Use:

These devices are indicated for patients with:

- Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
- Previous tibial condyle or plateau fractures with loss of anatomy or function.
- Varus or valgus deformities.
- Revision of previous arthroplasty procedures.

These devices are indicated for cemented use only.

The Zimmer Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K122529

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)